The Effects of Primary Stent Implantation vs. Percutaneous Transluminal Angioplasty on the Femoro-popliteal Artery Deformations due to Leg Flexion

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Introduction

The long-term outcomes of endovascular therapy in the femoro-popliteal (FP) arterial tract has been adversely effected by high restenosis rates. The hypothesis has been that the poor clinical outcomes result from mechanical factors induced by the movement of the leg during routine activities, such as walking or stair-climbing. The healthy FP artery deformations have been the subject of numerous studies[1,2]. However, these studies can only present limited information to improve current treatment methods and devices. To this end, it is crucial to analyze the deformations of arteries with Peripheral Arterial Disease (PAD) prior to and after endovascular treatment. Such studies would not only provide information on the arterial deformations of the target population, but also on the mechanical state of the artery resulting from different treatment modalities. Therefore, the aim of this study was to estimate the in-vivo deformations of 35 FP arteries with PAD prior to endovascular surgery and after primary stent implantation and Percutaneous Transluminal Angioplasty (PTA).

Patient Demographics & Image Acquisition

> **35 patients**

Age (Mean ± SD)	69 ± 10
Gender	
- Male	20
- Female	15
Fontaine stage	IIB
Calcification	
- Moderate	23
- Severe	12
Lesion length (mm) (Mean ± SD)	69 ± 9
Total occlusions	18

Region of the lesion	
- Common Femoral Artery to Mid/Distal SFA	1
- Proximal to Mid SFA	2
- Proximal to Distal SFA	3
- Mid SFA	5
- Mid to Distal SFA	11
- Distal SFA	6
- Distal SFA to Popliteal Artery	1
- Popliteal Artery	6

# of patients treated with PTA	17
- Non-coated balloons	15
- Drug-coated balloons	2
# of patients treated with stents	18
- Pulsar-18	6
- Everflex	9
- Zilver-PTX	5
- Xpert	1

> A lightweight calibration phantom was attached to the patients' thighs using a strap

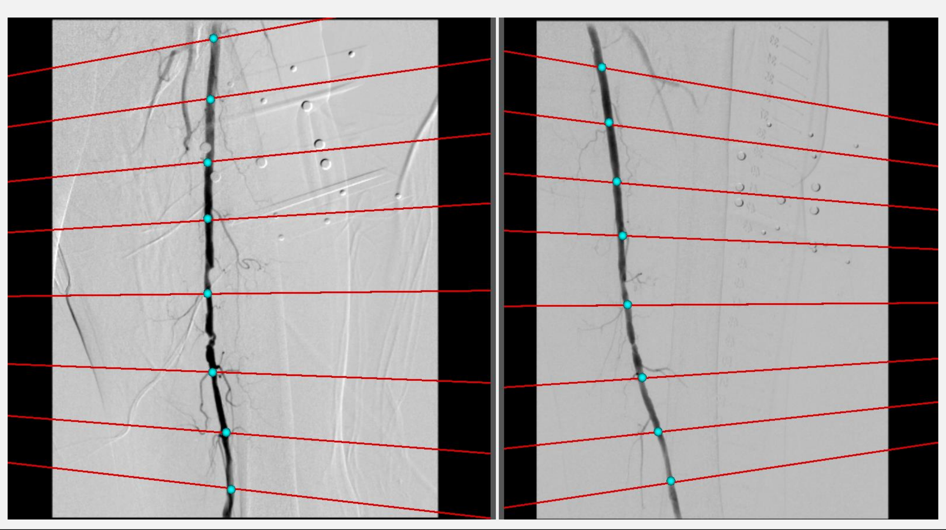
> A set of two angiographic images was acquired
- Seperated by a view angle of 45-60 degrees

- With the leg **straight** & knee/hip **flexion** of 70°/20°

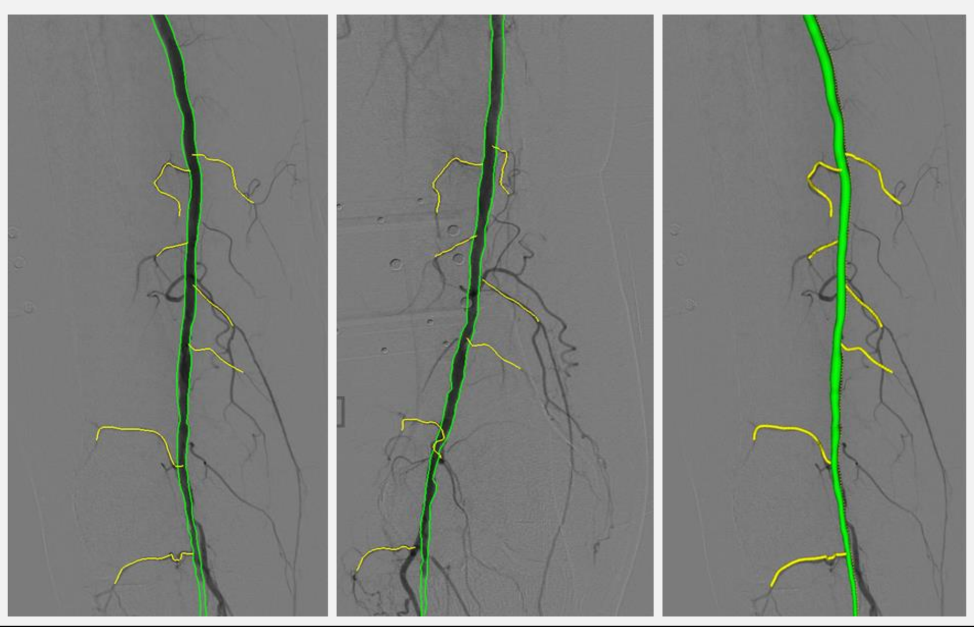
> Acquisitions performed **before** treatment and **after** either stent implantation or PTA

2D/3D Reconstruction & Quantification of Arterial Deformations

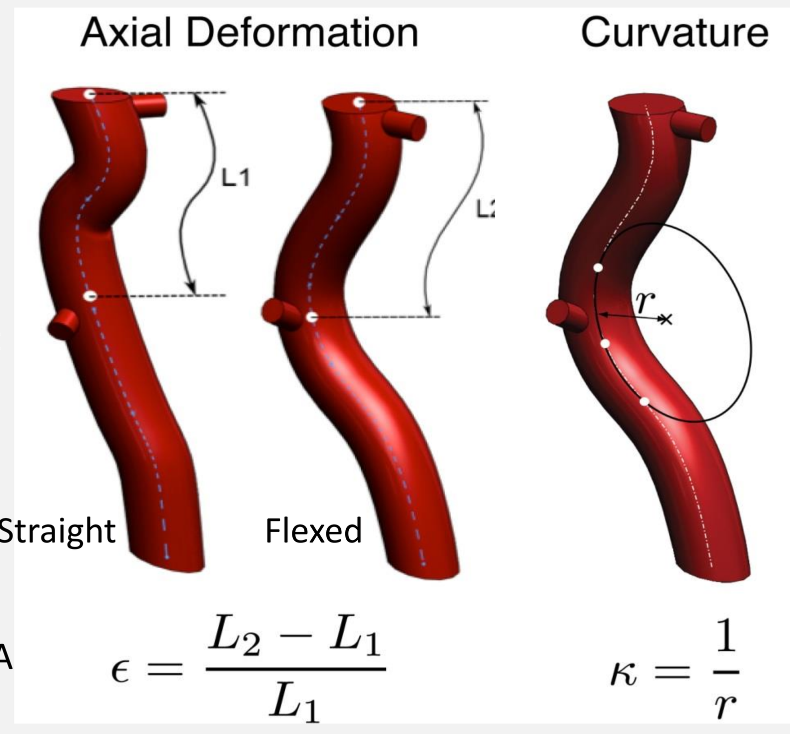
> **3D reconstruction of the arterial centerline**
- Calibration of the two images via the the phantom
- Images related to each other by the epipolar constraint
- Segmentation of the artery by 2D contour extraction



- Computation of the arterial centerpoints
- Triangulation of the 2D centerpoints to a 3D position



> **Arterial deformations**
- Based on a method by Choi[1]
- Calculations directly performed on reconstructed arterial centerlines
- Centerlines divided into **3** segments:
  - **Proximal** to lesion/treated region
  - Lesion/treated region
  - **Distal** to lesion/treated region
- Paired t-tests to assess the effects of leg flexion & stent implantation and PTA on arterial deformations



Results

Reconstruction Accuracy

The average forward projection error: 1.18 ± 0.28 mm

The average backward reconstruction error: 1.03 ± 0.15 mm

Arterial Deformations

Pre-Angio	Axial Deformation (%)	Curvature Change (cm^{-1}) Mean	Curvature Change (cm^{-1}) Maximal
Proximal to lesion	-5.4 ± 2.0	0.03 ± 0.04	0.10 ± 0.09
Lesion	-5.5 ± 3.2	0.04 ± 0.05	0.15 ± 0.12
Distal to lesion	-11.9 ± 4.0	0.10 ± 0.11	0.25 ± 0.20

Post-Balloon	Axial Deformation (%)	Curvature Change (cm^{-1}) Mean	Curvature Change (cm^{-1}) Maximal
Proximal to lesion	-4.4 ± 3.6	0.01 ± 0.02	0.05 ± 0.05
Lesion	-7.4 ± 5.3	0.06 ± 0.06	0.19 ± 0.12
Distal to lesion	-11.6 ± 4.3	0.15 ± 0.17	0.25 ± 0.21

Post-Balloon	Axial Deformation (%)	Curvature Change (cm^{-1}) Mean	Curvature Change (cm^{-1}) Maximal
Proximal to lesion	-8.7 ± 8.7	0.08 ± 0.10	0.18 ± 0.19
Lesion	-3.2 ± 2.9	0.03 ± 0.04	0.16 ± 0.14
Distal to lesion	-9.3 ± 6.7	0.09 ± 0.07	0.24 ± 0.18

> **Prior to** and **following** endovascular therapy, leg flexion caused:
- Shortening of the artery
- **Increase** in the mean and maximal curvatures

> The **ballooned arteries** exhibited increased shortening compared to **their stented counterparts** within the lesion

> Average curvature values in both straight and flexed positions were similar **before** and **after** treatment within/distal to the lesion

Discussion & Conclusion

> The deformations of the FP arteries are primarily affected by leg flexion[4]

> Arterial shortening differs between stent types
- With Zilver-PTX, the artery shortened less compared to the Everflex and Pulsar-18 fitted arteries

> The choice of the treatment method has a statistically significant effect on the post-interventional axial deformations

> The choice of the treatment method does not influence the overall bending behavior of the FP arteries

> **Arterial kinking**

Angiographic images of the femoropopliteal (FP) arteries of 3 patients acquired prior to PTA (a, c, e) and following primary stent implantation (b, d, f) and with a hip/knee flexion of 20°/70°.

> Depending on the anatomical position of the stents (e.g. Distal SFA & popliteal artery), the additional axial stiffening of the arteries may lead to **chronic kinking**
- Within 6 months, 20% of the patients had restenosis, with 4 of them exhibiting arterial kinking

> For peripheral arteries, a **'leave-nothing behind'** approach is recommended
- PTA is not associated with kinking
- If bail-out stenting is absolutely necessary, current stent designs should be improved to allow for additional shortening

References

[1] Choi et al. 2009. *Ann. Biomed. Eng.*

[2] Klein et al. 2009. *Catheter Cardiovasc. Interv.*

[3] Schumman et al. 2016. *J. Vasc. Intv. Rad.*

[4] Gokgol et al. 2016. *J. Endovasc. Ther.*